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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,538	08/17/2001	Steve J. D. Bell	37070/205236	5069

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,538	BELL ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2005 and 28 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7 and 12* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on 11-28-2005 is acknowledged. Claim 5 has been amended. Claims 1-4 and 8-11 have been canceled. Claim 12 has been added. Claims 5-7 and 12 are pending.

Newly submitted claim 12 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The elected invention is drawn to methods of inducing an immune response utilizing calcium phosphate particles (Group II of the restriction requirement) whereas newly added claim is drawn to the calcium phosphate particles themselves (Group I of the restriction requirement).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 12 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Consequently, claims 5-7 are currently under examination.

Claim Rejections Withdrawn

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the terms "substantially spherical shape" and "substantially smooth surface" is withdrawn in light of the amendment thereto.

The rejection of claims 5 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "induce immunity in a patient" is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 5-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-12 of copending Application No. 10/824,097 is maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 5-7 of the instant application are drawn to methods for inducing "immunity" in a patient comprising the administration of calcium phosphate particles that are at least partially coated with a "pharmacologically active agent". Claims 10-12 of copending application 10/824,097 are drawn to methods of inducing an immune response in a patient comprising the administration of calcium phosphate particles that are at least partially coated with an allergen and constitute a specific embodiment that renders the genus (i.e. the claims of the instant application) obvious. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has indicated that they will file a terminal disclaimer upon the allowance of the pending claims.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 5-7 under 35 U.S.C. 102(b) as being anticipated by Nuwayser (U.S. Patent 5,648,097) is maintained for reasons of record.

The instant claims are drawn methods of inducing an immune response in a patient utilizing calcium phosphate nanoparticles that are least partially coated and or impregnated with an antigen. Said particles are optionally used in compositions comprising said particles and a pharmaceutically acceptable carrier and other excipient wherein said particles are delivered to a mucosal surface.

Applicant argues:

1. Nuwayser is not relevant as the amended claims are drawn to "nanoparticles" in contrast to the "microparticles" disclosed by Nuwayser (said particles having a diameter range from 1 micron to several millimeters in diameter".

2. Nuwayser is not relevant as his particles are not delivered to mucosal surfaces but are injected into the patient.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, the particles of the instant invention are disclosed to have a diameter of 300nm to 4000 nm (4 microns) [see page21, lines19-20 of the specification].Since there is an overlap in claimed particles sizes and those disclosed by Nuwayser, Nuwayser is still relevant.

With regard to Point 2, as Nuwayser contemplates the delivery of his calcium phosphate particles by suppository as evidenced by Figure 2 and column 5 , line 66 to column 6, line 4).

As outlined previously, Nuwayser discloses methods for adsorbing biologically active compounds to calcium phosphate particles wherein the resulting particles serve as controlled release drug delivery vehicles (see abstract, column 5 lines 16-36). Moreover, Nuwayser discloses that said particles are substantially spherical and substantially smooth (see column 3, lines 52-54). Nuwayser further discloses that the biologically active agent or drug can include multitude of compounds including antigens and vaccines. Finally, it should be noted that the disclosure by Nuwayser contemplates application to mucosal surfaces as the disclosed "biologically active agents" include antihistamines and decongestants (see column 6, lines 13-18).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ROBERT A. ZEMAN
PATENT EXAMINER

February 15, 2006